

K101714

1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Herbert Crane
Director, Global Regulatory Affairs

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Date of Submission: June 17, 2010

Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3630)

Trade or Proprietary
or Model Name: NobelProcera Ti Abutment Thommen Platforms

Legally Marketed Devices: Nobel Biocare - NobelProcera Ti Abutment (K091756)
Thommen Medical AG – SPI Easy 4.0 Abutment (K071457)
Thommen Medical AG – SPI Dental Implant Abutments (K031747)

AUG 31 2010

Device Description:

Nobel Biocare's NobelProcera Ti Abutment Thommen Platforms is an endosseous dental implant abutment. The abutment attaches directly to Thommen dental implants and provides a platform for restoration.

Nobel Biocare's NobelProcera Ti Abutments are designed and made individually to fit the individual requirements for each patient. The NobelProcera Ti Abutments are made entirely of titanium or titanium/vanadium alloy.

The abutments fit the Thommen SPI implant systems platform 3.5, 4.0, 4.5, 5.0, 6.0.

Indications for Use:

The NobelProcera Ti Abutments Thommen Platforms are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Thommen Medical SPI 3.5, 4.0, 4.5, 5.0, and 6.0 implants.

Summary of testing to demonstrate safety and effectiveness

Non-clinical test data was used to support the decision of safety and effectiveness. Clinical testing was not necessary. Non-clinical testing consisted of analysis of platforms to identify worst-case test samples and performance of fatigue testing of the worst-case samples in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. The testing indicates that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

Substantial Equivalence Comparison to Predicate Devices

ATTRIBUTE	CANDIDATE	PREDICATE	PREDICATE
	NobelProcera Ti Abutment	Thommen SPI Easy 4.0 Abutment (K071453)	Thommen Medical AG SPI Easy 4.0 Abutment (K091756)
Design/construction	Patient specific / machined	Patient specific / machined	Patient specific / machined
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Platform compatibility	<u>Thommen</u> <u>SPI implant systems platform</u> <u>3.5, 4.0, 4.5, 5.0, 6.0</u>	<u>Nobel Biocare</u> <u>Bränemark NP, RP, WP</u> <u>Replace NP, RP, WP, 6.0</u> <u>Active NP, RP</u>	<u>Thommen</u> <u>SPI implant systems platform</u> <u>4.0</u>
Device Material	CP Titanium	Titanium/vanadium alloy	CP Titanium
Indications for Use	The NobelProcera Ti Abutments are premanufactured prosthetic components directly connected to endosteous dental implants and are intended for use as an aid in prosthetic rehabilitation.	The NobelProcera Ti Abutments are premanufactured prosthetic components directly connected to endosteous dental implants and are intended for use as an aid in prosthetic rehabilitation.	The Thommen SPI Easy 4.0 Abutment is intended to be used in conjunction with SPI System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Nobel Biocare AB
C/O Mr. Herbert Crane
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

AUG 31 2010

Re: K101714

Trade/Device Name: NobelProcera Ti Abutment Thommen Platforms
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 2, 2010
Received: August 3, 2010

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2- Mr. Crane

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3

Indications for Use

K101714

510(k) Number (if known): K101714

Device Name: NobelProcera Ti Abutment Thommen Platforms

Indications For Use:

The NobelProcera Ti Abutments Thommen Platforms are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Thommen Medical SPI 3.5, 4.0, 4.5, 5.0, and 6.0 implants.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Re: Mulley for HSP
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101714 000020